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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/932,503   | 08/17/2001  | Tulin Morcol         | 37070/207071        | 6972             |
| 23370  | 7590        | 10/04/2005           | EXAMINER            |                  |
| JOHN S. PRATT, ESQ<br>KILPATRICK STOCKTON, LLP<br>1100 PEACHTREE STREET<br>ATLANTA, GA 30309 |             |                      | ZEMAN, ROBERT A     |                  |
|  |             | ART UNIT             |                     | PAPER NUMBER     |
|  |             |                      |                     | 1645             |

DATE MAILED: 10/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |
|------------------------------|------------------------|---------------------|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |
|                              | 09/932,503             | MORCOL ET AL.       |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |
|                              | Robert A. Zeman        | 1645                |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 14 July 2005.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 1-11 and 18 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 12-17 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 4-11-2005
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_

**DETAILED ACTION**

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7-14-2005 has been entered.

The amendment filed 7-14-2005 is acknowledged. Claim 12 has been amended. Claims 13-18 have been added.

Newly submitted claim 18 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the instant invention is drawn to a method of delivering a therapeutic agent utilizing particles comprising a calcium phosphate core, a therapeutic agent and casein whereas claim 18 is drawn to a method of delivering a therapeutic agent utilizing particles comprising a calcium phosphate core, a therapeutic agent, casein and polyethylene glycol. The particles used are patentably distinct hence any methods utilizing them are patentably distinct as well.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 18 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

In summary, claims 1-18 are pending. Claims 1-11 and 18 have been withdrawn from consideration as being drawn to non-elected inventions. Claims 12-17 are currently under examination.

***Information Disclosure Statement***

The Information Disclosure Statement filed on 4-11-2005 has been considered. An initialed copy is attached hereto.

***Priority***

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. [1] as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 09/496,771, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The instant claims are drawn to the use of particles comprising a calcium phosphate core, a therapeutic agent associated with said core and a layer of

casein that at least partially covers said core. While the prior-filed application discloses particles comprising a calcium phosphate core and a therapeutic agent, said application fails disclose the use of casein. Therefore, the prior-filed application does not provide support for the claimed invention and hence cannot be relied upon to support a priority claim.

*New Grounds of Rejection*

**35 USC § 103**

Claims 12-17 are rejected under 35 U.S.C. 103(a) as being obvious over Bell et al. (U.S. Patent 6,355,271) in view of Corrigan et al. (WO 99/03451).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the

reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The instant invention is drawn to a method of delivering a therapeutic amount of a therapeutic agent to a patient comprising orally delivering one or more particles wherein said particles comprise a calcium phosphate core, a therapeutic agent associated with said core and a casein layer that at least partially covers said core.

Bell et al. disclose particles comprising a calcium phosphate core particles and a therapeutic agent (biologically active material) associated with said calcium phosphate core (see abstract). Bell et al. further disclose the novel calcium phosphate core particles having a material coated on the surface of the core particles, and/or dispersed or impregnated within the core particles, to methods of making them, and to methods of using them. Non-limiting examples of a suitable material to be at least partially coated on the surface of the core particle or impregnated therein include one or more of the following: antigenic material, natural immunoenhancing factors, polynucleotide material encoding immunogenic polypeptides, or therapeutic proteins or peptides (see column 5, lines 34-44). Moreover, Bell et al. disclose that the therapeutic protein can be insulin (see column 14, lines 47-49). Finally, Bell et al. disclose need for alternate methods of insulin delivery and outline the problems associated with various forms of delivery (including oral delivery)[see column 4, lines 30-47].

Bell et al. differs from the instant inventions in that they do not disclose the use of casein as a coating substance. Corrigan et al. disclose the use casein in pharmaceutical compositions to reduce the irritating effects of the active ingredient (therapeutic compound) [see page 5 lines 10-

14] and to provide controlled release pharmaceutical compositions for oral administration (see page 6, lines 4-6). Corrigan et al. further disclose that casein can be used in conjunction with multiple formulation "forms" including granules (i.e. particles) [see page 7, lines 20-32]. Consequently, it would have been obvious for one of skill in the art to use the casein disclosed by Corrigan et al. in conjunction with the calcium phosphate particles disclosed by Bell et al. in order to take advantage of the reduced gastrointestinal irritation and increased drug delivery associated with the use of casein. Moreover, the skilled artisan would have been additionally motivated to combine the teachings of the aforementioned references in hopes of filling the need for alternative insulin delivery methodologies. One of ordinary skill in the art would have had a high expectation of success since Corrigan et al. disclose that casein can be used with "granular formulations". Consequently, the combination of the cited references renders all the rejected claims obvious.

### ***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



**ROBERT A. ZEMAN**  
**PATENT EXAMINER**

September 30, 2005